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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/987,675 | 11/15/2001 | Lynne Canne | 03504.283B | 7481 |

7590 06/02/2004

LINIAK BERENATO LONGACRE & WHITE
SUITE 240
6550 ROCK SPRING DRIVE
BETHESDA, MD 20817

EXAMINER

GUPTA, ANISH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 1654 |

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/987,675 | CANNE ET AL. |
| | Examiner Anish Gupta | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23-26 and 29-56 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 23-26 and 29-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

1. Applicants amendment filed, 11-15-01, is acknowledged. Claims 1-26 and 28 were canceled, claim 27 was amended, and claims 29-60 were added to instant application. Claims 27, 29-60 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 23-26 and 29-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. US 6,326,468 in view of Barstow et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the instant application are drawn to an kit for producing assembled polypeptides comprising a solid support having bound thereto a partially or completely unprotected polypeptide wherein the peptide is bound to the solid support via the N-terminus and the peptide has a C-terminal end of a thioacid or thioester of the formula —COSR (see claim 1 and 41). The US Patent claims a method for producing polypeptides comprising binding a partially or completely unprotected first peptide segment to a solid phase via a linker to form a solid phase bound peptide

segment, wherein the peptide segment is bound to the solid support via the N-terminus using a linker, similar to the claimed invention, and the peptide has a C-terminal end of a thioacid or thioester of the formula –COSR (see claim 1). Note that the modifications and/or characteristics defined in the subsequent claims of the instant application are similar to the characteristics defined in the US Patent. For example, claims 23-40 of the instant application disclose similar features to claims 8-11 of the US patent in the type of solid support used, the length of peptide segments, the source of the peptide, and the type of backbone in the peptide (natural vs. non-natural). The difference between the US Patent and the instant application is that the US Patent does not disclose a kit with different containers as recited in claim 23.

However, the use of kits in peptide synthesis is known and conventional. For example, Barstow et al. teaches kits for peptide synthesis, which contains a separate container for each reagents (see col. 7, lines 50-65). Further, the packaging of regents in self-contained containers would render the practice of synthesis easier since all of the materials are easily available and separated. Therefore it would have been obvious to separate all of the regents in parts (a), (b), and (c) in separate containers in practicing the invention of the US Patent because making kits for peptide synthesis is well known in the art and the use of containers would make the method of synthesizing the peptide in the US Patent less complicated.

3. Claim 23-26 and 29-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27 and 29-60 of copending Application No. 09/987,655 in view of Barstow et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

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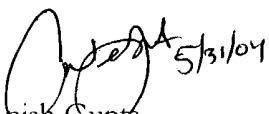
The claims of the instant application are drawn to an kit for producing assembled polypeptides comprising a solid support having bound thereto a partially or completely unprotected polypeptide wherein the peptide is bound to the solid support via the N-terminus and the peptide has a C-terminal end of a thioacid or thioester of the formula -COSR. The US provisional application discloses and apparatus for making the same polypeptides using the same solid support, fragments peptides, and unprotected peptides segments. Claims of the provisional application are identical to the instant application minus the words "kit" and "container."

However, the use of kits in peptide synthesis is known and conventional. For example, Barstow et al. teaches kits for peptide synthesis, which contains a separate container for each reagents (see col. 7, lines 50-65). Further, the packaging of regents in self-contained containers would render the practice of synthesis easier since all of the materials are easily available and separated. Therefore it would have been obvious to separate all of the regents in parts (a), (b), and (c) in separate containers in practicing the invention of the US Patent because making kits for peptide synthesis is well known in the art and the use of containers would make the method of synthesizing the peptide in the US Patent less complicated.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupra
Patent Examiner

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